Attorney Docket No.: 66631,8001,US01

#### **REMARKS**

## I. Status of the Claims

Claims 1, 4, 5, 8-20 and 22-29 are pending. Claims 15-17 and 29 are withdrawn. With this amendment, claims 1 and 5 are amended, claim 4 is canceled and new claims 30-31 are added.

## II. Amendments to the Specification

Paragraph [0029] on page 9 of the specification as originally filed is amended to delete reference to "prevention" as indicated herein. No new matter is added by way of this amendment.

# III. Amendments to the Claims

Claim 1 is amended to incorporate the limitations of claim 4. Specifically, claim 1 as amended recites "wherein at least 75 wt. % of the active agent in the dosage form is released within the time period."

Claim 1 is further amended to delete the phrase, "following said administering to a patient in the fed mode, the dosage form is retained in the upper gastrointestinal tract for a time period of about 4 to 9 hours."

Claim 5 is amended to depend on claim 1.

New claims 30-31, directed to administering a dosage form which is retained in the upper gastrointestinal tract for a specified time period, find support in original claims 2 and 3. New claims 30-31 depend on amended claim 1.

Accordingly, the claim amendments do not introduce new matter.

# IV. Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 18-20 under 35 U.S.C. § 112, first paragraph for lack of enablement. Specifically, the Examiner stated that while the specification is enabling for "treating a human patient suffering from a bacterial infection," the specification does not reasonably provide enablement for "preventing or curing a human patient suffering from a bacterial infection." The Examiner then further states that claims 18-20 are drawn to a method of treating a human patient suffering from a bacterial infection and notes that the

term "treatment" and "treat" are defined in the specification as including prevention of the occurrence of symptoms and/or their underlying cause.

Without acquiescing, Applicants have amended paragraph [0029] on page 9 of the specification to delete reference to "prevention of the occurrence of symptoms and/or their underlying cause," and "prevention" of a particular disorder.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112.

### V. Allowable Subject Matter

In the Office Action dated January 20, 2010, the Examiner indicated that claims 4-5, 8-10, and 22-28 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 1 is amended to recite the limitations of claim 4. Claim 4 is presently canceled. Claims 5, 8-10 and 22-28 either directly or indirectly depend on amended claim 1.

Applicants have presently deleted from claim 1 recitation of the limitation, "the dosage form is retained in the upper gastrointestinal tract for a time period of about 4 to 9 hours." Applicants remind the Examiner that this limitation was added to claim 1 in the response filed September 26, 2009, after the Examiner indicated that claim 3, which recited "the dosage form is retained in the upper gastrointestinal tract for a time period of about 4 to 9 hours," would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims (see page 5 of the Office Action dated July 7, 2009). However, the Examiner subsequently stated in an Examiner-initiated interview on December 31, 2009, that the addition of this limitation to claim 1 would not overcome the double-patenting rejection (see the Examiner-Initiated Interview Summary document for the interview of December 31, 2009, mailed on January 20, 2010).

Accordingly, Applicants understand that claim 1 as presently amended to recite the limitations of claim 4, will be deemed allowable by the Examiner.

Applicants further note that claims 11-14 depend directly or indirectly from amended claim 1, which the Examiner indicated would be allowable. Because claim 1 as presently amended includes all of the limitations of claim 4, any claims dependent on amended claim 1 should also be deemed allowable. Applicants respectfully request indication of same.

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# VI. <u>Double-Patenting Rejection</u>

Claims 1, and 11-14 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 19, 20 and 40 of U.S. Patent No. 6,340,475.

Claim 1 is amended to incorporate the limitations of claim 4. Claims 11-14 depend directly or indirectly from claim 1. As stated above, because amended claim 1 now recites subject matter deemed by the Examiner to be allowable, claims 1 and 11-14 should be found allowable.

Applicants respectfully request withdrawal of the double-patenting rejection.

### VII. <u>Conclusion</u>

For the reasons above, Applicants respectfully submit that the pending claims are novel and non-obvious over the cited art. Furthermore, Applicants respectfully submit that all criteria for patentability have been satisfied and the pending claims are in full condition for allowance. A Notice of Allowance is therefore respectfully requested.

If the Examiner has any questions or believes a telephone conference would expedite the prosecution of this application, Applicants request that the Examiner call the undersigned at (650) 590-1919.

No fees are believed due with this communication. However, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No.:50-4616.

Respectfully submitted.

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